K132519

DEC - 6 2013

510(k) Summary

Date prepared:	August 5, 2013
Submitter:	Stryker Craniomaxillofacial 750 Trade Center Way Portage, MI 49002 USA
Contact:	Rob Yamashita Phone: (269) 389-4258 / Fax: (269) 329-2235 rob.yamashita@stryker.com
Proprietary Name:	Stryker Customized Mandible Recon Plate Kit
Common Name:	Bone Plate
Proposed Regulatory Class:	Class II
Product Codes:	JEY

Predicate Device: Predicate devices for intended use, indications for use, and technical characteristics are:

1. Stryker NewGen/Universal Mandibular System - K014263
2. Synthes Patient Specific Plates - K122647

The predicate device for the patient-specific ordering, designing, and logistics process is:

3. Stryker PEEK Customized Cranial Implant Kit - K121153

Intended Use: The Customized Mandible Recon Plate Kit is intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions.

Indication for Use: The Customized Mandible Recon Plate Kit is indicated for use in primary mandibular reconstruction with bone graft, temporary bridging until delayed secondary reconstruction and secondary mandibular reconstruction.

Device Description:

The Customized Mandible Recon Plate Kit includes customized, patient specific implants, the Customized Mandible Recon Plates. Additionally, the kit includes the Instruction for Use (IFU) and a printed version of the Design Proposal approved by the surgeon prior to plate manufacture. It may include an anatomical model, named Mandible Model.

The Customized Mandible Recon Plates (CMRP) and the corresponding Mandible Model are designed and manufactured for one specific patient. The products are ordered by a surgeon on a patient-by-patient basis over an internet platform referred to as the "eRequest Lifecycle online ordering system" which was already cleared with K111065 for ordering patient specific polymer implants to correct trauma and/or defects in mandibular, maxillofacial, or craniofacial bone. Based on patient specific anatomical data (CT-scan) and input from the surgeon, a virtual mandible recon plate with its specific dimensions (profile heights, length and 3D run of the plate, number and position of screw holes and bar strengthening) is created using the Customized Mandible Recon Plate Design Process (CMRP-DP) including the Plate Design Software (PDS).

Screenshots of the virtual plate are then presented to the surgeon in the Design Proposal (pdf-file). After the surgeon approves the Design Proposal via the above mentioned eRequest Lifecycle online ordering system, the Customized Mandible Recon Plate, as well as the Mandible Model (if ordered by the surgeon), are manufactured according to the specifically set design requirements. Once the manufacturing process is finalized and the devices are cleaned, they are packed, labeled and shipped to the location specified during the ordering process.

The CMRP implant is compatible with the Stryker Universal Mandibular System. Additionally, Stryker offers customized cutting and drill guides for use with the Customized Mandible Recon Plate.

Technological and Operational Characteristics:

The Stryker Customized Mandible Recon Plate Kit is similar to its Predicate Devices in the following technological and operational characteristics:

- Material: The Subject Device is made of biocompatible commercially pure titanium (CP Ti Grade 2); Predicates 1 and 2 are made of pure titanium.

- Design: The transfer of CT patient data to a manufacturing process resulting in an individualized implant fulfilling the specific requirements of the patient is identical to the subject device and Predicate 3 and similar to Predicate 2.
  The final patient specific plate for mandibular reconstruction itself is similar to the stock plates of Predicate Device 1. Predicate Device 2 provides patient specific plates for mandibular

	reconstruction, therewith being similar to the Subject Device. The Subject Device is offered in 2.0mm and 2.8mm profile height, whereas the Predicate Devices 1 and 2 range from 1.5mm to 2.8mm profile height.
• Principal of Operation:	The basic operational principle of the Subject Device, as well as Predicate Devices 1 and 2, is the stabilization of mandibular reconstruction. The method of site preparation and fixation are identical for both the Subject Device and the referenced Predicate Devices.
• Packaging:	The Subject Device and all Predicate Devices are delivered non-sterile.

Clinical Testing:

No clinical testing was performed to support this submission.

Non-Clinical Testing:

The Stryker Customized Mandible Recon Plate Kit proved to meet acceptance criteria in all evaluations conducted for biocompatibility, cleaning, sterilization, multiple reprocessing, residual moisture after sterilization, MRI conditional, transportation, clinical transportation; mechanical strength of plate, mechanical strength of locking mechanism between plate and screw and handling of system (end user & end product test).

Substantial Equivalence to Predicate Devices:

The Stryker Customized Mandible Recon Plate Kit combines the principles of individualized design configuration with the PEEK Customized implant as one of the predicate devices and the principles of operation with the other two Predicate Devices 1 and 2. Its intended use and its indications for use are nearly identical to these. Material and technological characteristics are similar to the legally marketed Predicate Devices 1 and 2. The ordering, design and logistical process of the Subject Device is nearly identical to the one of Predicate Device 3.

Performance Testing:

Verification and Validation (V&V) evaluation has been performed on the Subject Device in the following categories: biocompatibility, cleaning validation, sterilization validation, multiple reprocessing, residual moisture after sterilization, MRI conditional,

transportation validation, clinical transportation, mechanical strength of plate, mechanical strength of locking mechanism between plate and screw, and handling of system (end user & end product test). The Subject Device fulfilled all set acceptance criteria for each category in accordance with either ISO or ASTM specifications, or internally predetermined acceptance criteria if no standards were applicable. All applied ISO standards are listed below.

Reference	Title
Biocompatibility	
DIN EN ISO 10993 ff as valid 2013	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management system
Sterility/Reprocessing	
ISO 11138-1:2006	Sterilization of health care products - Biological indicators - Part 1: General requirements
DIN EN ISO 11737-1:2009	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
DIN EN ISO 11737-2:2009	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process
DIN EN ISO 14161:2011	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results
DIN EN ISO 14937:2009	Sterilization of health care products – general criteria for characterization of a sterilizing agent and development, validation and routine control of a sterilization process
EN ISO 15883-1:209	Washer-disinfectors: General requirements, terms and definitions and tests
DIN EN ISO 17664:2004	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
DIN EN ISO 17665-1:2006	Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
DIN ISO/TS 17665-2:2009	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Stryker Craniomaxillofacial
Mr. Rob Yamashita
Associate Manager, Regulatory Affairs
750 Trade Center Way Ste 200
Portage, MI 49002

Re: K132519
Trade/Device Name: Stryker Customized Mandible Recon Plate Kit
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: October 22, 2013
Received: November 4, 2013

Dear Mr. Yamashita:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Erin I. Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Device and
Radiological Health

Enclosure

stryker

Craniomaxillofacial

510(k) Number (if known): K132519

Device Name: Stryker Customized Mandible Recon Plate Kit

Indications For Use: The Customized Mandible Recon Plate Kit is intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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